

### **REMARKS**

In the Office Action dated March 9, 2004, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

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| Group I.   | Claims 47, 48 and 51-55, drawn to a plant delta-6 desaturase, and cells and plants transformed therewith, classified in class 536, subclass 23.6.     |
| Group II.  | Claims 47, 49 and 51-55, drawn to a bacterial delta-6 desaturase, and cells and plants transformed therewith, classified in class 536, subclass 23.7. |
| Group III. | Claims 47, 50 and 51-55, drawn to a fungal delta-6 desaturase, and cells and plants transformed therewith, classified in class 536, subclass 23.74.   |

The Examiner contends that Groups I-III are drawn to molecules that differ structurally and require different searches of sequences. The Examiner also contends that each of the molecules of Group I-III can be made and used separately, independent of each other.

In order to be fully responsive to the Examiner's requirement for restriction, Applicant provisionally elects to prosecute the subject matter of Group I, Claims 47, 48 and 51-55, drawn to a plant delta-6 desaturase, and cells and plants transformed therewith. Applicant reserves the right to file one or more divisional applications directed to the non-elected subject matter in this application.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicant hereby traverses the Examiner's requirement for restriction and requests reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

More specifically, Applicant respectfully submits that Groups I-III are drawn to nucleic acid molecules that are related to each other both structurally, i.e., having similar sequences, and functionally, i.e., all encoding a delta-6 desaturase. Applicant respectfully submits that Groups I-III are clearly related to each other and are merely different aspects of a single invention.

Applicant respectfully suggests that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all three defined groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,



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